Examination Procedure Outline for

Jeweler and Prescription Scales – Electronic

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It is recommended that this outline be followed for electronic digital indicating scales and balances used in prescription and jeweler applications. This outline includes requirements for Class I and Class II prescription scales with a legal for trade counting feature (See page 5E-10). Requirements that apply only to scales marked with an accuracy class designation are indicated with an asterisk (*). Nonretroactive requirements are followed by the applicable date in parentheses.

Prescription scales are often located and used in areas where controlled substances are stored. Access to these areas, except by qualified personnel, is generally prohibited. Do not enter any restricted areas unless authorized to do so by personnel having proper authority to grant such access.

SAFETY NOTES

When excerpting this Examination Procedure Outline for duplication, the EPO Safety Annex (Safety Considerations and Glossary of Safety Key Phrases) should be duplicated and included with this outline.

Prior to beginning any inspection, the inspector should read and be familiar with the EPO Safety Annex - "Safety Considerations and Glossary of Safety Key Phrases." The terms and key phrases in each safety reminder of this outline are found in the glossary the EPO Safety Annex. The inspector is reminded of the importance of evaluating potential safety hazards prior to an inspection and taking adequate precautions to avoid personal injury or damage to the device. As a minimum, the following safety precautions should be noted and followed during the inspection.

Safety policies and regulations vary among jurisdictions. It is essential that inspectors or servicepersons be aware of all safety regulations and policies in place at the inspection site and to practice their employer's safety policies. The safety reminders included in this EPO contain general guidelines useful in alerting inspectors and servicepersons to the importance of taking adequate precautions to avoid personal injury. These guidelines can only be effective in improving safety when coupled with training in hazard recognition and control.

Clothing Personal Protection Equipment e.g., Safety Shoes

Electrical Hazards Support – for Scale and Test Weights

First Aid Kit Transportation of Equipment

Lifting

Also: Chemicals and Hazardous Materials or Obstructions

Equipment List:

Mass Standards Required ¹	Special Handling Equipment	
Class I Scales: OIML E-2, ASTM 1, or standards of greater accuracy.	Clean lint-free and dust-free gloves	
Class II Scales: OIML F-1, ASTM 3, or standards of greater accuracy.	Tweezers	
Class III Scales: NIST Class F, or standards of greater accuracy.	1 weezers	
Unmarked Scales: Use standards of the proper level of accuracy that comply with NIST Handbook 44 Fundamental Consideration as detailed in footnote 1.	Ash-free, acid-free filter paper	

Note: The conversion tables for units of measurement commonly indicated on jewelers and prescription scales are listed in Appendix A to EPO No. 5E. Verify the performance of the scale at multiple test points when different units of measurement are in commercial use for a particular application.

Special care is required when handling mass standards to maintain the accuracy level needed to properly test most prescription and jewelers scales and scales marked Class I or Class II.

- 1. Never touch standards with bare hands or otherwise contaminate standards by placing them on dirty surfaces.
- 2. Always wear suitable gloves or use tweezers when handling precision standards to prevent substances (oils, lint, moisture, etc.) from adhering to their metal surfaces.
- 3. Special filter papers are available and should be used to prevent contact with dirty surfaces.
- 4. Proper cleaning methods are to be used.
- 5. Exercise care in storing and transporting standards to avoid physical damage.

Inspection:

1.	Accessibility for inspection, testing, and sealing	G-UR.2.3.	
2.	Zero-load balance as found	UR.4.1.	
	Zero indication		
		S.1.1., S.1.1.1. (a), S.1.1.1.	
		(b) (1/1/93)	
	Zero-load adjustment	S.2.1.1., S.2.1.2.	
	Zero tracking (scales manufactured between 1/1/81 and 1/1/07)	S.2.1.3.1.(a)	
	Zero tracking (scales manufactured on or after 1/1/07)	S.2.1.3.2.(b)	

3. Marking:

Identification (Refer to the list of required markings indicated in the table

¹ In accordance with NIST Handbook 44, Fundamental Considerations Section 3 paragraph 3.2., the combined error and uncertainty of any standard used for testing must be less than one-third the applicable device tolerance. The use of the mass standards indicated for each of the scale accuracy classes listed will ensure conformance with this fundamental consideration.

that follows)	G-S.1., G-S.1.1. (1/1/04),
	S.6., S.6.3., Table S.6.3.a,
	Table S.6.3.b.

List of Required Markings for Jeweler and Prescription Scales			
Manufacturer's ID or Name	Certificate of Conformance (CC) Number or CC Addendum Number and Prefix (1/1/03)		
Model Identifier	Special Application (1/1/86)		
Model Identifier Prefix and Acceptable Abbreviations (1/1/03)	Nominal Capacity ¹		
Serial Number (1/1/68)	Nominal Capacity and Value of Scale Division, "d" Displayed Together (1/1/83)		
Serial Number Prefix (1/1/86)	Value of the Verification Scale Division, "e" if different from the value of the scale division "d" (1/1/86) ²		
Acceptable Abbreviations for "Serial" and "Number" (1/1/01)	Temperature Limits (1/1/86) ³		
Current Software Version or Revision Identifier for Not Built-For-Purpose, Software-Based Devices (1/1/04)	Accuracy Class (1/1/86)		
Version or Revision Identifier Preface and Acceptable Abbreviations for Not Built-For-Purpose, Software Based Devices (1/1/07)	Scales Equipped with a Counting Feature ⁴		

The nominal capacity of a prescription scale that is not marked with an accuracy class designation can be assumed to be ½ apothecary ounce, unless otherwise marked. (Reference Scales Code paragraph N.6.)

Required only when the temperature range on the NTEP CC is narrower than and within -10 °C to 40 °C (14 °F to 104 °F). For Class I and Class II scales, temperature limits are permitted to be specified in operating instructions.

⁴ Class I and Class II prescription scales equipped with a <u>legal for trade</u> counting feature must be marked: "Counting Feature For Prescription Filling Only."

All other scales equipped with a counting feature must be marked: "The Counting Feature Is Not Legal For Trade." The statement must be displayed on both the operator and customer sides of the scale.

Note: Be aware that the required marking information included in this table was extracted from the 2007 edition of NIST Handbook 44 and is susceptible to change in succeeding editions.

Marking (continued):

Remanufactured device or main elements	2)
Interchange or reversal of parts	
Operational controls, indications, and features	
LetteringG-S.7.	
Visibility of identification	

4. General Considerations:

Selection of equipment	
	UR.1.
Appropriateness of design	
Typical class for weighing applications	UR.1.1., Table 7a*
Accuracy class designation and parameters	S.5.1.* (1/1/86), S.5.2.*
	(1/1/86)
Nominal capacity (applies to unmarked prescription scales)	N.6.
Recommended minimum load	U.R.3.1.*
Maximum load	U.R.3.2.
Permanence.	

Be aware that some scales may be designed with a constant verification "e" in addition to a scale division "d" that changes value within the weighing range of the scale. Because "e" is constant, these scales are not considered multi-range scales.

5.	Installation	G-UR.2.1.
	Indicating or recording element	G-UR.2.2.
	Position of equipment (not applicable to prescription scales)	G-UR.3.3.
	Initial zero-setting mechanism	S.2.1.5. (a), S.2.1.5.(b)
		(1/1/09)
	Supports	UR.2.1.
	Check to ensure that scale supports provide a firm foundation for th	e scale under
	all loading conditions, including loading of the platform to device	capacity!
	Level indicating means and condition	S.2.4. (1/1/86), UR.4.2.
	Customer indications	S.1.8.3.
6.	Design of indicating and recording elements:	
	Value of the scale division	
		(1/1/89), G-S.5.3.,
		G-S.5.3.1., UR.1.3.
		(1/1/86), UR.1.3.1.
		(1/1/86)
	Indicated and recorded representation of units (Appropriate abbreviations):	C C F C 1 (z)
	Equipment manufactured on or after January 1, 2008	
	Equipment manufactured prior to January 1, 2008	G-3.3.6.1. (b)
	on page 3 of this EPO)	\$ 5.3
	Value of the verification scale interval	
	Value of the tare division	
	Tare mechanism.	
	Combined Zero-Tare ("0/T") key	
	Damping means	
	Prepackaging scales	
7.	Design of the weighing element	S.4.
8.	Security and sealing:	
	Adjustable components	S.1.10.
	Adjustment mechanisms designed to be sealed	
	Provision for sealing (does not apply to Class I scales)	G-S.8. (1/1/90), S.1.11.(a)
		(1/1/79), S.1.11. (b)
		(1/1/90), S.1.11.(c)
		(1/1/95)
	Manual weight entries (applicable to scales used for direct sales):	
	when gross weight indication is at zero	
	when gross or net weight indication is at zero	S.1.12. (1/1/05)
9.	Maintenance, use, and environmental factors:	
	Facilitation of fraud	
	Protection from environmental factors	
	Method of operation	
	(scales having special designs)	
	Maintenance of equipment	
	Abnormal performance	
	Scale modification	
10.	Assistance	
10.	Assistance	G-UK.4.4.

Pretest Determinations:

For Class I and II scales equipped with a verification scale division (e) that does not equal the value of the displayed scale division (d), verify that the relationship between "e" and "d" conforms to the expression:

$d < e \le 10 d$

For Class III scales that are marked with a manufacturer's designated verification scale division (e), verify that the value of "e" is <u>less than or equal</u> to the value of "d."

2. Tolerances:

Tolerance values:

Determine the number of scale divisions (n)² using the following formula:

$$n = \frac{\text{Scale capacity}}{\text{Value of the verification scale division (e)}}$$

Scales marked with an accuracy class	T.N.3.1., Table 6,
	T.N.3.2., T.N.4, T.N.5
Scales not marked with an accuracy class	T.1.1 Table T.1.1.

Test Notes:

1. Scales equipped with Automatic Zero-Tracking (AZT) Mechanism:

manufactured between 1/1/81 and 1/1/07	S.2.1.3.1.((a)
manufactured on or after 1/1/07	.S.2.1.3.2.0	(b)

To verify correct operation of an AZT feature on a scale in which the value of the scale division (d) is <u>equal</u> to the value of the verification scale division (e), (i.e., the scale manufacturer has not declared a verification scale division) complete step a. through step f. below.

- a. Zero the scale with no load on the platter.
- b. Apply <u>all at one time</u> test weights equal to 0.7 d.
- c. Verify that the indicator is continuously displaying the value of 1 d.
- d. Zero the scale with the 0.7 d test weights remaining on the platter.
- e. Remove the 0.7 d test weights all at one time.

 2 On a multiple range or multi-interval scale, the number of divisions for each range independently shall not exceed the maximum specified for the accuracy class. The number of scale divisions, n, for each weighing range is determined by dividing the scale capacity for each range by the verification scale division, e, for each range (i.e., do not add "n" for the ranges together). On a scale system with multiple load-receiving elements and multiple indications, each element considered shall not independently exceed the maximum specified for the accuracy class. If the system has a summing indicator, the n_{max} for the summed element shall not exceed the maximum specified for the accuracy class. (Table 3 footnote added 1997)

Rev-3/11 EPO 5E Page 6

EPO No. 5E

Counting Feature

- f. The scale must display a continuous behind zero indication using one of the following means:
 - display a value equal to minus 1 d;
 - blank the display; or
 - display error symbols that cannot be interpreted as a weight value

If the scale is equipped with a verification scale division (e) that is <u>not equal</u> to the value of the scale division (d), the value of "d" rather than "e" is used to calculate the maximum permissible amount of weight that can be rezeroed during this test. However, in instances where multiplying the value of the scale division (d), whether or not the value of "d" and "e" are equal, by 0.7 results in a value that is smaller than the smallest available test standard, a field test of the AZT feature is not possible.

Be aware that step a. through step c. verify the correct operation of an AZT feature on the positive side of zero while step d. through step f. verify the correct operation of an AZT feature behind zero. A continuous display of 1 d (in step c.) and a continuous display of a behind zero indication (i.e., in accordance with any of the means noted in step f.) confirms the correct operation of an AZT feature on both sides of zero. However, if the displayed indication is zero following the completion of step b. or step e., the AZT feature may not be functioning properly. In this case, verify the feature is not functioning properly by repeating the AZT test before rejecting the device.

2.	If the scale is equipped with a semiautomatic zero-setting mechanism
	(i.e., pushbutton zero), a pushbutton tare feature, or a ticket printer,
	verify the correct operation of motion detection

4. Check	proper design of	of tare auto-clear,	if scale is so	equipped	S.2.3. (1/1/83)
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Note: A test for discrimination should be performed when environmental conditions permit and when the test standards available for testing are adequate in amount and are of suitable denominations. Steps a. through d., of the **Procedures for Testing Discrimination at or Near Zero Load** and **Procedures for Testing Discrimination Near Maximum Capacity** indicated below, specify the total amount and the minimum denominations of the test standards needed to properly perform a discrimination test.

Procedures for Testing Discrimination at or Near Zero Load for a Scale, where d = e

The procedures for testing discrimination near zero load on scales equipped with a scale division value (d) that is equal to the value of the verification division (e), (i.e., d = e) are indicated in step a. through step f. below and illustrated in Figure 1.

- a. With the scale on zero, place decimal weights on the scale equal to the value of 1 d.
- b. Zero the scale and place a load equal to the value of 5 d on the platter.
- c. Remove the decimal weights in 0.1 d increments until the indication flickers between the values representing 4 d and 5 d. If the indication does not flicker but indicates a steady 4 d value, add 0.1 d. If the scale indicates 5 d, it is at the breakpoint in the zone of uncertainty. (remove the 0.1 d if it was added to the 4 d value to verify the breakpoint)
- d. Add a test load equal to 1.4 d to the scale.

EPO No. 5E

Counting Feature

- e. The indication should read a stable 6 d (i.e., the addition of 1.4 d should change the displayed indication 2 d)
- f. If the scale passes the discrimination test at a load near zero, a discrimination test should also be performed near the maximum capacity of the scale.

Example: Discrimination Test near Zero Load for a Scale, where d = e

Scale capacity: 610 x 0.01 g

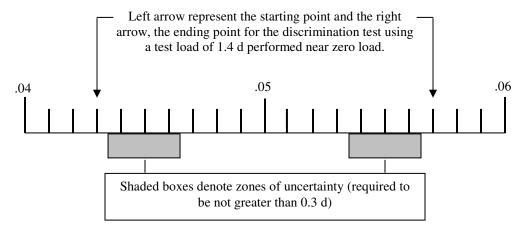


Figure 1

Procedures for Testing Discrimination near Maximum Capacity for a Scale, where d = e

The procedures for testing discrimination near maximum load on scales equipped with a division value (d) that is equal to the value of the verification division (e), are indicated in step a. through step f. below and illustrated in figure 2.

- a. With the scale on zero and no load on the load-receiving element, apply test weights equal to 1.4 d and zero the device.
- b. Add a test load sufficient in amount to cause the scale to indicate a stable value near maximum capacity.
- c. With the scale indication stable at a near capacity test load, add test standards in 0.1 d increments until the indication continually flickers back and forth between the indication that was stable and the next higher increment. Then add 0.1 d to cause the indication to become stable at the higher of the two flickering increments.
- d. Remove the 1.4 d test weights.
- e. To pass the discrimination test near maximum capacity, the removal of the 1.4 d test weights should cause the indication to change (decrease) by 2 d.

Example: Discrimination Test Near Maximum Capacity for a Scale, where d = e

Scale capacity: 610 x 0.01 g

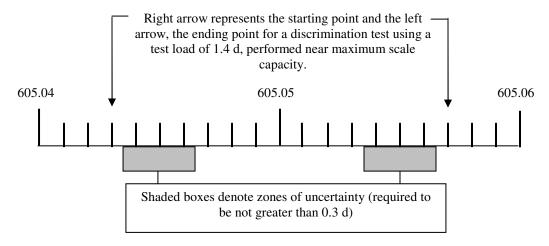


Figure 2

Procedures for Testing Discrimination at or Near Zero Load and Near Maximum Load for a Scale, where $\mathbf{d} \neq \mathbf{e}$

The procedures for testing discrimination near zero load and near maximum scale capacity when the value of the minimum scale division (d) is not equal to the value of the minimum verification scale division (e), are as follows:

- a. Zero the scale with no load on the platter.
- b. Apply a test load equal to 2 e to the platter and observe the displayed indication.
- c. Apply an additional test load of 2 d to the platter and observe the displayed indication.
- d. The addition of 2 d in step c. must increase the displayed indication by 2 d.
- e. For the discrimination test at or near maximum capacity, apply a test load near scale capacity, then remove 2 d and observe the change in the displayed indication.
- f. The displayed indication must change by 2 d when a test load of 2 d is removed.
- g. The results of these tests confirm that a scale is able to detect small changes in weight being added or removed from the platter over the scale's entire weighing range.

Test:

- 1. Level condition and Zero-load balance (verify before beginning the increasing-load test)
- 2. Increasing-load test (test loads approximately centered on the platter)......N.1.1.

For scales marked with an accuracy class, test at several points in each tolerance range including at or near the highest test load that can be applied to the scale without the tolerance increasing to the next tolerance range. For scales not marked with an accuracy class, test at several points to capacity, including test loads at or near one-quarter, one-half, and three-quarters of scale capacity and at full capacity.

The shift test can be conducted during the increasing load test once one-third capacity test load is achieved.

³ NIST Handbook 44 Scales Code paragraph N.1.3.7.(a) defines one-third nominal capacity test load as test weights in amounts of at least 30% of scale capacity, but not to exceed 35% of scale capacity.

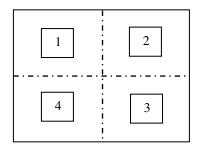
EPO No. 5E

Counting Feature

Shift Test Pattern

(One-third capacity test load)

The numbered boxes identify the positions for placing the shift test load.



4 2

Figure 3. Rectangular Platter Shift Test Pattern.

Figure 4. Circular Platter Shift Test Pattern.

4. RFI/EMI (if a problem is suspected)

Radio Frequency Interference

Electromagnetic Interference	G-N.2., G-UR.1.2.,
6	G-UR.3.2., G-UR.4.2.,
	N.1.6., T.4., T.N.9*

....G.S.5.2.2.(a), G-S.5.4., T.N.5.

For scales marked with an accuracy class and having a total number of scale divisions (d) or verification scale divisions (e), if "e" has been declared, greater than or equal to 100 000 for Class I scales or 10 000 for Class II scales, test with loads equal or near the highest value of each tolerance band. For example, on a Class II scale, test at loads equal or near 20 000 d and 5 000 d if a verification scale division has not been declared and at or near 20 000 e and 5 000 e if a verification scale division has been declared. For all other scales, test at one-half maximum test load applied during the increasing-load test.

It is recommended that the additional requirements in this outline be followed for a Class I or Class II prescription scale equipped with a legal for trade counting feature. The counting feature is based on commodity weight, therefore, accuracy of the weighing function must be verified before conducting a test of the counting feature.

Inspection:

1. Marking:

A scale with a legal for trade counting feature shall be capable of indicating zero in the count mode of operation.

An operational counting feature is only legal for prescription filling applications on a compliant Class I or Class II device.

A prescription scale with a legal for trade counting feature must be marked:

"Counting Feature for Prescription Filling Only"

Class I or Class II prescription scales equipped with an operational counting feature that does not comply with all applicable NIST Handbook 44 requirements for the count feature must be marked on both the customer and operator's side:

"The Counting Feature is Not Legal for Trade."

Pretest Determinations:

2. Determine the scale's maximum counting capacity (i.e., the maximum number of pieces the scale is capable of indicating) by inserting the appropriate corresponding values marked on the device into the following formula:

nominal capacity
minimum individual piece weight

For example: Given a scale marked as follows:

Capacity: 610 x 0.01 g
Minimum individual piece weight: 0.03 g
Minimum sample piece count: 10 pieces

Using the formula, the maximum count value in pieces is calculated as follows:

$$\frac{610 \text{ g}}{0.03 \text{ g/piece}} = 20 333.3333 \text{ pieces}$$

Then truncate the result to the nearest whole number of 20 333 pieces.

3. Select at least three count values to verify the count accuracy of a legal for trade counting feature similar to that illustrated below:

A count value between 90 and 100 pieces inclusive;

- a count value between 180 and 200 pieces inclusive; and
- a count value equal or near the scale's maximum counting capacity as determined in 2. above.

Note: When choosing the count value near a scale's maximum counting capacity, select a whole number that is slightly lower than the maximum possible count. For example, one possible choice at the maximum end of the counting capacity for the scale described above is 20 300. The resulting value of 20 300 is slightly less than the actual truncated value of 20 333 and is less likely to introduce rounding errors when converted to a

corresponding weight value. The result is also more practical when selecting denominations of test standards for use in testing the count accuracy than if 20 333 were used.⁴

Additional count values representative of an operator's normal and customary use of a scale in filling prescriptions may also be selected as possible test points when verifying count accuracy.

4. Convert the selected count values to weight by multiplying each count value by the minimum individual piece weight⁵ marked on the device.

Given the same device for this example, convert selected count values of 100, 190, and 20 300 pieces to weight using the formula: piece count x minimum individual piece weight = amount of test weight to be applied.

$$100 \times 0.03 \text{ g} = 3 \text{ g}$$

 $190 \times 0.03 \text{ g} = 5.7 \text{ g}$
 $20 300 \times 0.03 \text{ g} = 609 \text{ g}$

Test Notes:

The combined error and uncertainty in any test standard used for testing must be less than one-third the applicable tolerance. Refer to the list of acceptable standards for use in testing precision scales on page 5E-2 of this EPO.

2. Special handling precautions for test standards:

Special care is required when handling mass standards to maintain the accuracy level needed to properly test most prescription and jewelers scales and scales marked Class I or Class II. Never touch standards with bare hands or otherwise contaminate standards by placing them on dirty surfaces. Always wear suitable gloves or use tweezers when handling precision standards to prevent substances (oils, lint, moisture, etc.) from adhering to their metal surfaces. Special filter papers are available and should be used to prevent contact with dirty surfaces. Proper cleaning methods are to be used. Exercise care in storing and transporting standards to avoid physical damage.

G-S.5.3.1., G-S.5.4 G-S.5.5., G-S.5.6.

⁴ When the 20 300 piece count is converted to weight by multiplying it by the scale's marked "minimum individual piece weight" of 0.03 g, the resulting weight value equals 609 g. If 20 333 is multiplied by this same factor, the resulting weight value equals 609.99 g. It would be considered acceptable to perform the test at 20 333 pieces using a test load of 609.99 g, providing test standards were available in small enough denominations for converting this count value to its exact equivalent in weight; however, it is easier and more practical to use test standards in denominations of whole grams.

⁵ Although the weight of an individual piece in any given prescription to be counted will often be greater than a scale's marked minimum individual piece weight, the sample used for the purpose of verifying count accuracy is established from minimum values (i.e., minimum individual piece weight and minimum sample piece count) marked on the device.

Test:

The counting feature test requires the scale meet all three test criteria listed in 1. through 3. below. It is first necessary to determine the "minimum sample size in weight" using the formula:

Minimum sample size in weight = minimum individual piece weight x minimum sample piece count

The values for "minimum individual piece weight" and "minimum sample piece count," must be appropriately marked and identified on a prescription scale equipped with a legal for trade counting feature.

Verify that the scale's counting feature will not accept a sample containing less than the "minimum sample piece count" by completing the following steps:

- a. Verify that the scale is in the counting mode of operation.
- b. With the scale operating in the counting mode, apply a sufficient load to the platter to cause the displayed indication to equal the "minimum sample size in weight."
- c. Attempt to input a sample piece count less than the "minimum sample piece count" marked on the device.
- d. The counting feature must reject the entry.

Verify that a scale's counting feature will not accept the entry of an individual piece weight that is less than the "minimum individual piece weight" by completing the following steps:

- a. Verify that the scale is in the counting mode of operation.
- b. With the scale operating in the counting mode, apply a sufficient load to cause the displayed indication to be less than the "minimum sample size in weight."
- c. Attempt to enter the "minimum sample piece count" marked on the device.
- d. The counting feature must reject the entry.

Complete the following steps in order to verify the accuracy of a legal for trade counting feature:

- a. Place the scale in the counting mode of operation.
- b. Zero the scale with no load on the platter.
- c. Apply a load sufficient in amount to cause the displayed weight indication to equal the value of the "minimum sample size in weight" as marked on the device.
- d. Enter the value of the "minimum sample piece count" as marked on the device using the keyboard or other input means.
- e. Remove the sample load that was applied in step c.; scale must indicate zero pieces.
- f. Apply test standards equivalent in value to each of the test points selected, including the test point near highest possible count.
- g. Observe the displayed count indication after each test point load is applied and verify that no count errors exceed the applicable tolerances indicated in Table T.N.3.10.
- h. Remove the entire test load; scale must indicate zero pieces.
- i. Return the scale to the weigh mode, and verify a zero balance indication.